Pandemic Influenza

Who should get vaccinations first?

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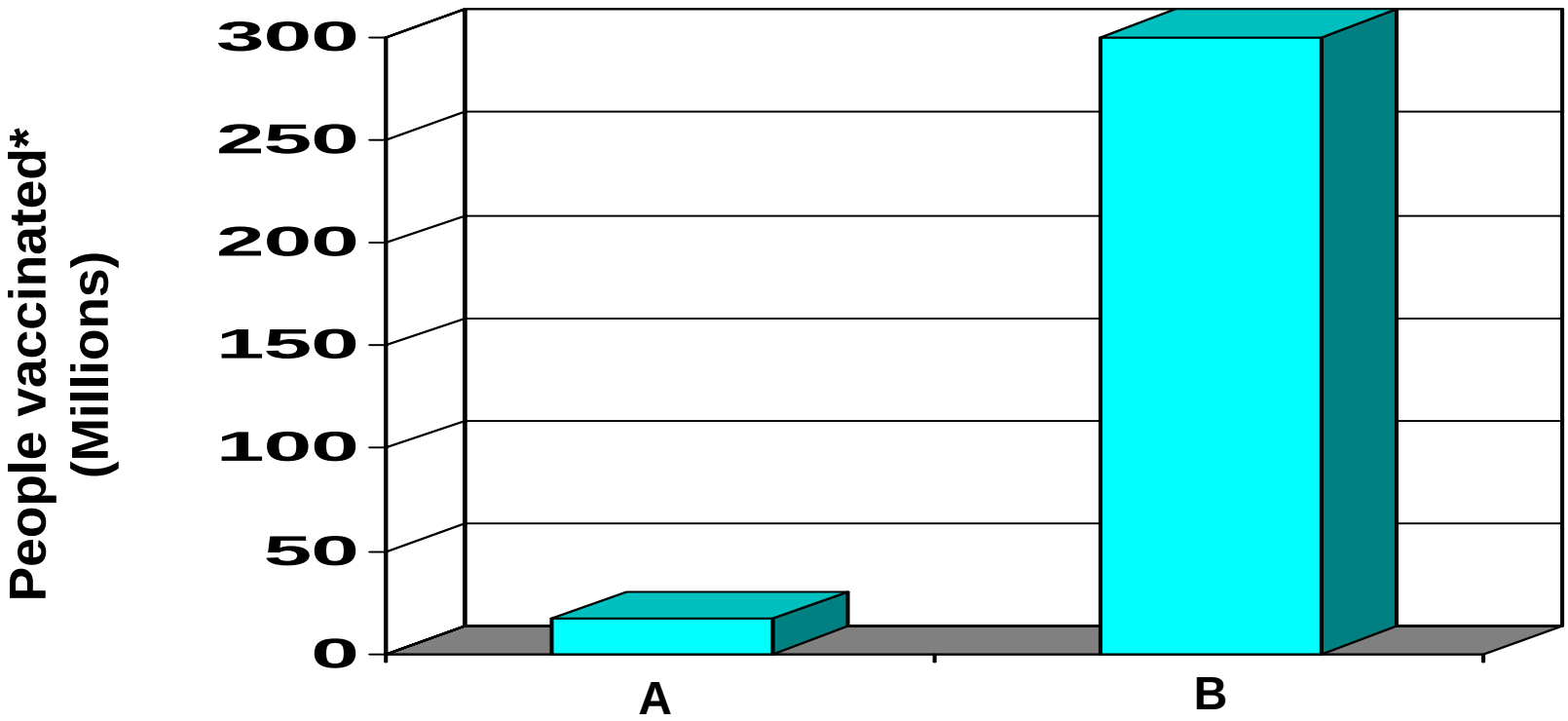
Issues to address

- Why prioritize pandemic influenza vaccinations?
- 2005 ACIP/NVAC process and recommendations
- Current prioritization process
  - Interagency working group
  - NIAC analysis
  - Public engagement and stakeholder meetings
- Next steps

Why do we need to decide who gets the vaccine earliest in a pandemic?

- Everyone will be susceptible
- U.S.-based production capacity currently is not sufficient to make vaccine rapidly for the entire population
- Earliest doses currently projected as becoming available at ~20 weeks after identification of the pandemic virus

Current U.S. pandemic influenza vaccine production capacity



A: Current annual U.S.-based capacity

B: National pandemic need

***Assumes 2 doses/person, 90 ug/dose**

Initiatives to increase pandemic influenza vaccine availability

- Increase vaccine production capacity
- Develop and license new vaccine production technologies (e.g., cell culture)
- Evaluate adjuvanted vaccine formulations

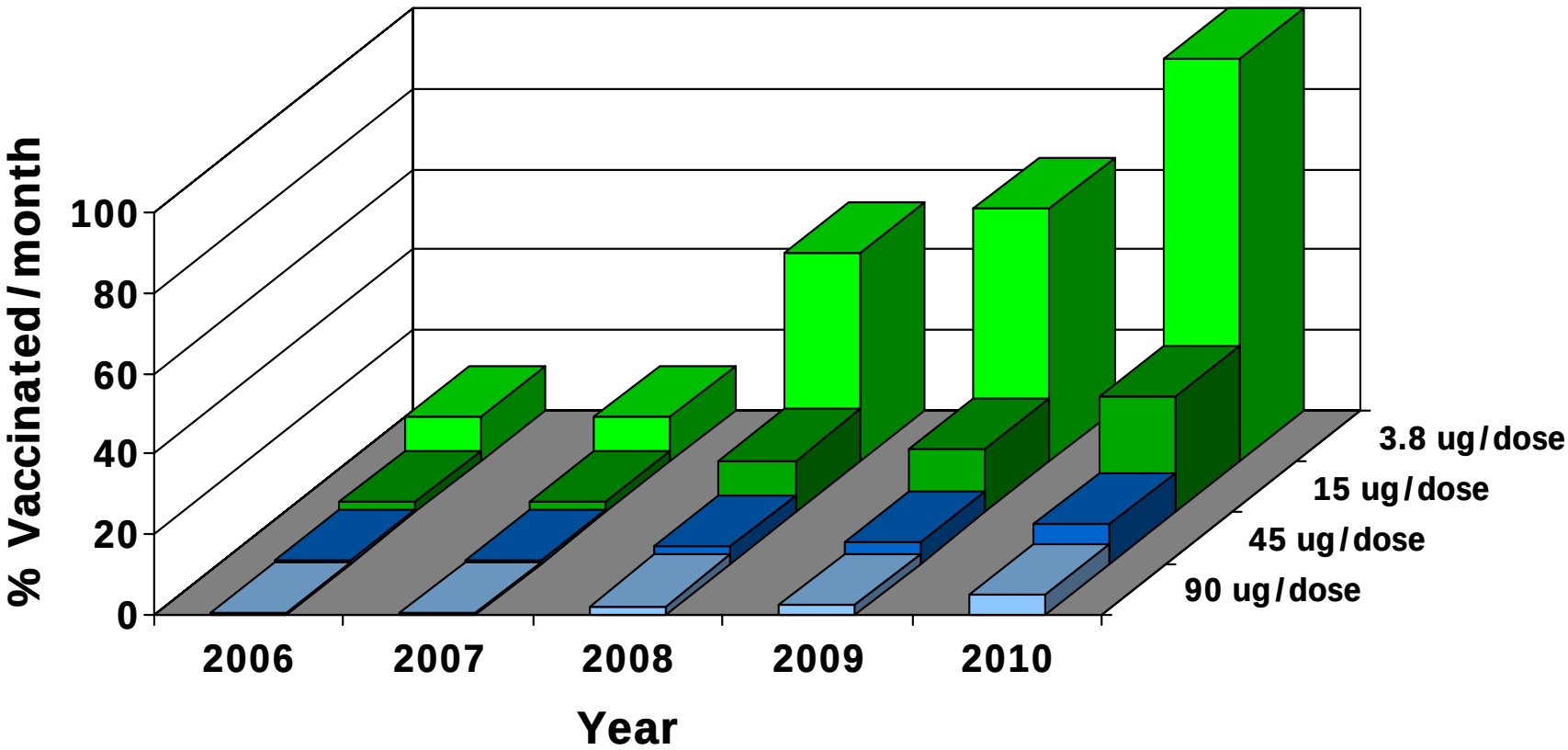
Potential effectiveness of H5N1 (Clade 1) vaccine formulations

Study/vaccine	Vaccine	Adjuvant	Age group	Titer ≥1:40
Treanor, Sanofi US	Split	None	18-64	90 ug - 54% 45 ug - 43%
Bresson, Sanofi France	Split	Alum	18-40	30 ug - 67%
Lin, Sinovac	Whole	Alum	18-60	10 ug - 78%
Unpublished, GSK	Split	ASO3	18-60	3.8 ug - >80%

All studies administer 2 doses separated by 3-4 weeks

Treanor, NEJM 2006; Bresson, Lancet 2006; Lin, Lancet 2006; GSK press release 7/26/06

Projected U.S.-based influenza vaccine production by year and antigen content



Previous pandemic vaccine prioritization activities: ACIP/NVAC

- Joint work of HHS vaccine advisory committees
- Process included consideration of
  - Vaccine supply and efficacy
  - Impacts of pandemic disease by age and risk group
  - Potential impacts on critical infrastructure
  - Potential impacts on health care
  - Ethics
- Recommendations included in the 2005 HHS pandemic plan
  - As guidance for State/local planning
  - To promote further discussions

ACIP/NVAC priority groups

Element and Tier	Personnel (1,000's)	Cumulative total (1,000's)
1A. Health care involved in direct patient contact + essential support	9,000	9,000
Vaccine and antiviral drug manufacturing personnel	40	9,040
1B. Highest risk group	25,840	34,880
1C. Household contacts of children <6 mo, severely immune compromised, and pregnant women	10,700	45,580
1D. Key government leaders +critical public health pandemic responders	151	45,731
2. Rest of high risk	59,100	104,831
Most CI and other PH emergency responders	8,500	113,331
3. Other key government health decision makers + mortuary services	500	113,831
4. Healthy 2-64 years not in other groups	179,260	293,091

Basis for ACIP/NVAC prioritization strategy

- Pandemic response goal of mitigating adverse health outcomes considered primary
- Pandemic severity assumptions
  - 20-30% attack rate; up to 1% case fatality rate
- Certain benefit of vaccinating high risk versus unclear benefit of vaccinating CI
  - Estimate of 10-15% absenteeism due to illness or caring for ill family members at pandemic peak
  - Much greater mortality risk among vulnerable persons than general population

Rationale for reconsideration of pandemic vaccine prioritization

- Public engagement meetings
  - Preserving essential services ranked as top goal
- Evolving planning assumptions
  - More severe pandemic; increased absenteeism
- Evolving pandemic response strategies
  - E.g., Community mitigation
- Additional analysis of critical infrastructures

Interagency pandemic vaccine prioritization working group

- Participants from federal agencies
- Process includes
  - Presentations on key issues and by key stakeholders
  - Consideration of ACIP/NVAC recommendations
  - Consideration of National Infrastructure Advisory Council recommendations on critical infrastructure
  - Public engagement meetings
  - Stakeholder meeting
  - Decision analysis process
  - Written comments

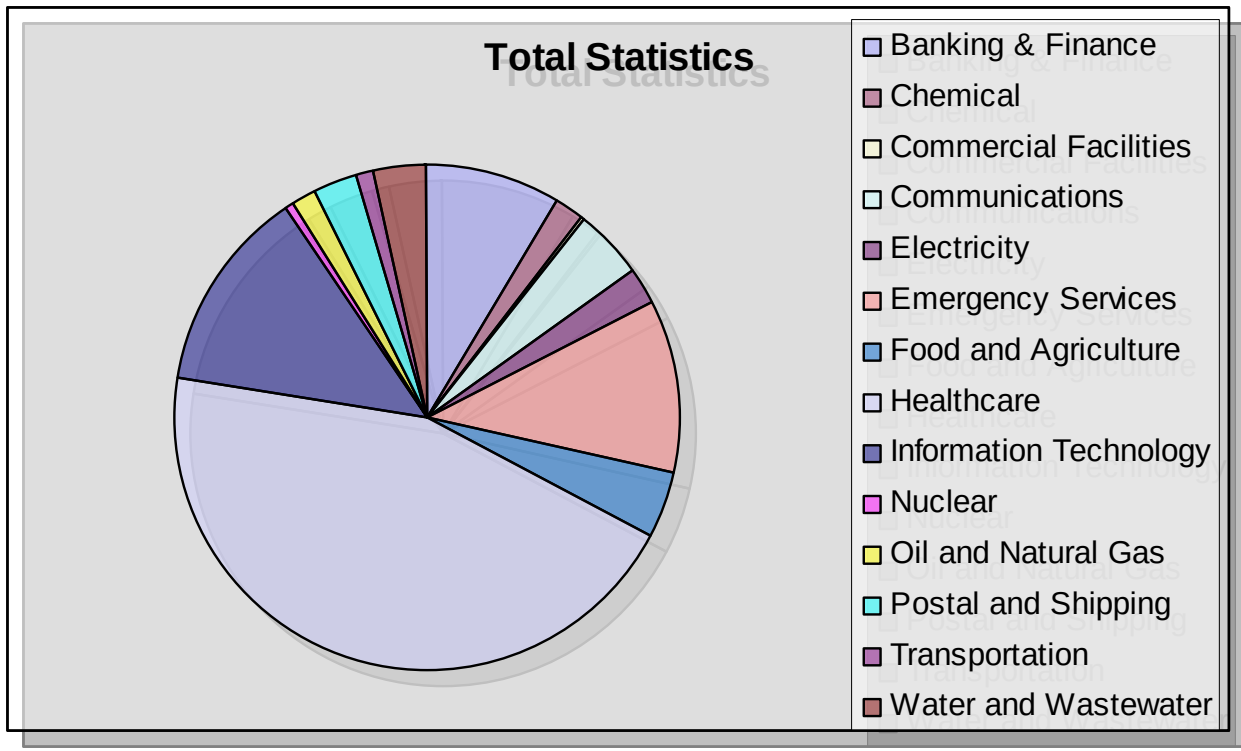
NIAC analysis of critical infrastructure (CI) for a U.S. pandemic

- Request for analysis from Secs. Leavitt & Chertoff
- Issues considered
  - Critical functions of CI and key resource (KR) sectors (maintain national & homeland security; ensure economic survival; maintain health & welfare)
  - Interdependencies between sectors
  - Workforces needed to maintain critical functions
- Process
  - Survey of CI/KR operators; review of existing data and plans, & interviews of subject matter experts

Identifying critical employee groups
Sector detail: all sectors, all tiers

Critical Employees: Tiers 1 -3

Banking & Finance: 1,562,000
Chemical: 322,618
Commercial Facilities: 84,000
Communications: 796,194
Electricity: 375,000
Emergency Services: 1,997,583
Food and Agriculture: 750,000
Healthcare: 6,999,725
Information Technology: 2,358,800
Nuclear: 86,000
Oil and Natural Gas: 328,674
Postal and Shipping: 464,744
Transportation: 198,387
Water and Wastewater: 608,000



TOTAL: 16,931,725

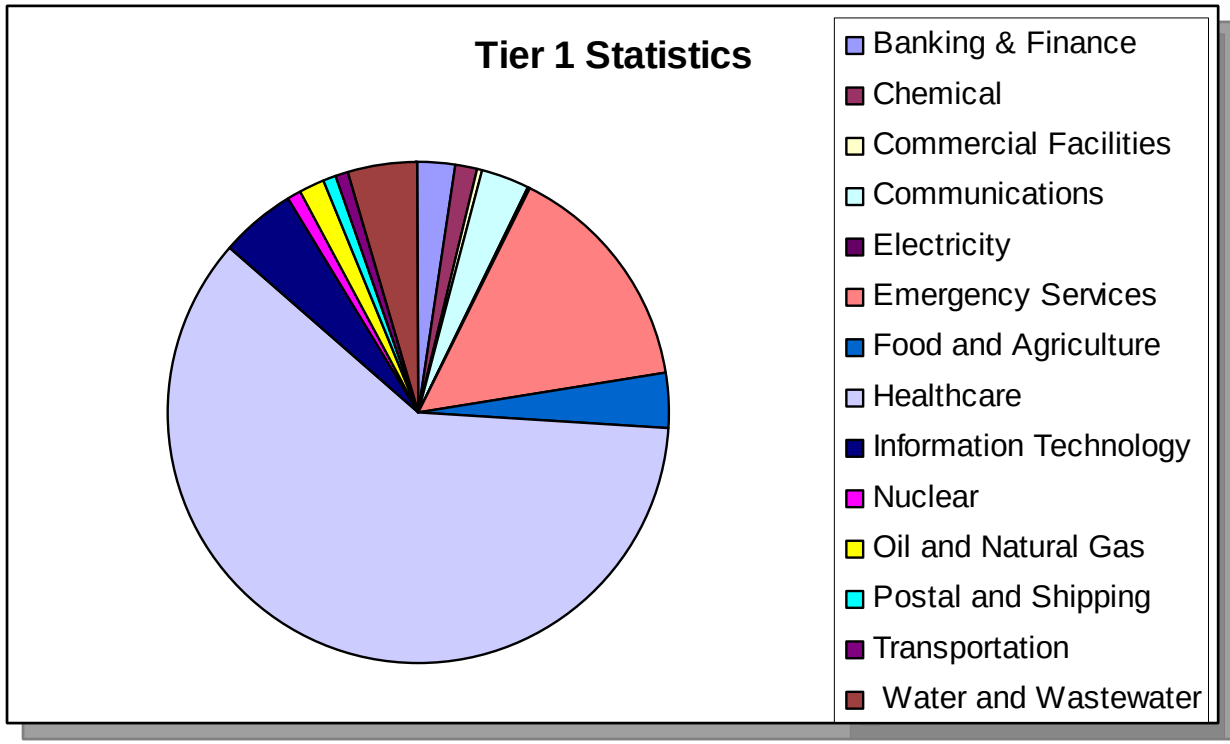
Notes:

a. *Numbers include Tier 1, Tier 2, and Tier 3 "essential" employees.*
b. *State and local government numbers removed from gross and priority workforce numbers.*

Identifying critical employee groups: all sectors, tier 1 only

Employees: Tier 1 Only

Banking & Finance: 417,000
Chemical: 161,309
Commercial Facilities: 42,000
Communications: 396,097
Electricity: 50,000
Emergency Services: 1,997,583
Food and Agriculture: 500,000
Healthcare: 6,999,725
Information Technology: 692,800
Nuclear: 86,000
Oil and Natural Gas: 223,934
Postal and Shipping: 115,344
Transportation: 100,185
Water and Wastewater: 608,000



TOTAL: 12,389,977

Notes:

a. *Numbers include Tier 1 "essential" employees only.*

b. *State and local government numbers removed from gross and priority workforce numbers.*

NIAC numbers: summary

- As a proportion of the CI/KR workforce (85 M)
  - Tier 1 = 14.6%; all 3 Tiers = 19.9%
- As a proportion of the U.S. population (300 M)
  - Tier 1 = 4.1%; all 3 Tiers = 5.6%
  - Excluding HC and ES, Tier 1 = 1.1% and all 3 Tiers = 2.6%

Public engagement and stakeholder meetings

- Objective: Consider goals of pandemic vaccination and assign values to each
- Approach
  - Background presentations
  - Group discussions
  - Electronic voting
- Participants
  - Las Cruces NM – ~108 persons; culturally diverse
  - Nassau Co., NY – ~130 persons; many older persons
  - DC – ~90 persons; government, CI sectors, community organizations

Assumptions for considering and weighing pandemic vaccination goals

- Severe 1918-like pandemic
  - But **no** assumption of increased mortality among young, healthy persons
- Uncertain vaccine timing and supply
- Other pandemic response measures
  - Border strategies
  - Community mitigation strategies
  - Antiviral treatment +/- prophylaxis
  - Planning by government and businesses

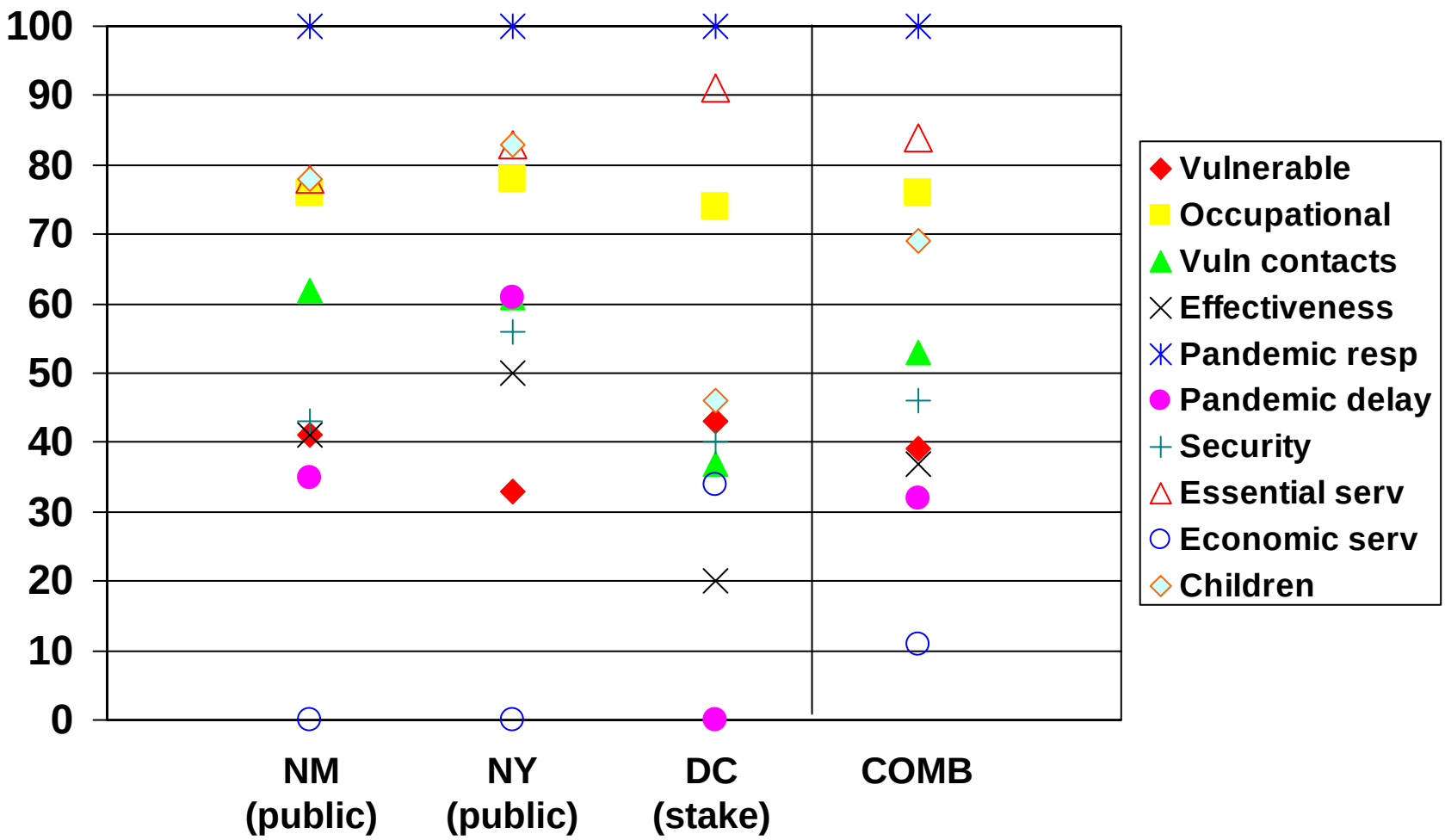
Weighting pandemic vaccination goals

We should prioritize vaccine to…	1	2	3	4	5	6	7
Reduce risk of severe illness/death	☐	☐	☐	☐	☐	☐	☐
Reduce occupational risk of infection	☐	☐	☐	☐	☐	☐	☐
Reduce risk of transmission to vulnerable persons (not protected by vaccine)	☐	☐	☐	☐	☐	☐	☐
Maximize vaccine effectiveness	☐	☐	☐	☐	☐	☐	☐
Protect persons providing pandemic response services	☐	☐	☐	☐	☐	☐	☐
Protect persons providing services to delay entry of pandemic into US	☐	☐	☐	☐	☐	☐	☐
Protect persons who maintain national and homeland security	☐	☐	☐	☐	☐	☐	☐
Protect persons providing essential community and government services	☐	☐	☐	☐	☐	☐	☐
Protect persons providing essential economic services	☐	☐	☐	☐	☐	☐	☐
Protect children	☐	☐	☐	☐	☐	☐	☐

Value of pandemic vaccination goals: public (Las Cruces, Nassau Co.) and stakeholder (DC) meeting results (7-point scale)

Vaccination goal: To protect…	Las Cruces	Nassau County	D.C.
People most likely to get sick or die	4.5	4.8	4.8
People most vulnerable due to jobs	5.8	5.6	5.9
People most likely to spread virus to unprotected	5.3	5.3	4.6
People most likely to be protected by the vaccine	4.5	5.1	4.0
People working to fight pandemic & provide care	6.7	6.0	6.8
People keeping pandemic out of the U.S.	4.3	5.3	3.3
People protecting homeland security	4.6	5.2	4.7
People providing essential community services	5.9	5.7	6.5
People providing essential economic services	3.0	4.2	4.5
Children	5.9	5.7	4.9

Normalized scores for vaccination goals



Summary and interpretation of public engagement and stakeholder results

- The 4 most highly rated goals were the same at all meetings
- Values underlying those goals were
  - Maintaining critical societal functions
  - Protecting those who would help others during the pandemic
  - Protecting children as “our future”
- Most other goals were considered moderately important
  - Ratings and rank order varied between meetings

Pandemic vaccine prioritization interagency working group next steps

- Draft prioritization guidance
- Obtain comments and suggestions, March – April
  - Public & stakeholder meetings
  - Web based public engagement
  - Written comments
  - ACIP & NVAC input
- Finalize guidance by May
- The working group also will consider
  - Pre-pandemic vaccine prioritization
  - Approach to modifying guidance at the time of a pandemic